Calithera Biosciences Reports CB-839 Phase I Solid Tumor Combination Data at the American Society of Clinical Oncology Annual Meeting

June 6, 2016

- *Future development to focus on renal cell carcinoma and triple negative breast cancer*
- *Calithera to host investor webcast on June 6, 2015 at 6:30 p.m. CT*

SOUTH SAN FRANCISCO, Calif., June 06, 2016 (GLOBE NEWSWIRE) -- Calithera Biosciences, Inc. (Nasdaq:CALA), a clinical stage biotechnology company focused on the development of novel cancer therapeutics, announced that clinical data from its lead product candidate CB-839, a first-in-class glutaminase inhibitor, was presented at the American Society of Clinical Oncology Annual Meeting (ASCO), in Chicago, Illinois. The data demonstrated the clinical activity, tolerability and unique mechanism of action of CB-839 in patients with renal cell carcinoma and triple negative breast cancer (TNBC).

“CB-839 is the first tumor metabolism drug to target a pathway that starves cancer cells by directly depriving them of a key nutrient. The combination data presented at ASCO demonstrates that CB-839 can safely be added to standard of care therapeutics to treat solid tumors with the potential to improve clinical outcomes,” said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera.

CB-839 in Renal Cell Carcinoma

Dr. Funda Meric-Bernstam from MD Anderson Cancer Center will present a poster titled, “Phase I study of CB-839, a small molecule inhibitor of glutaminase, alone and in combination with everolimus in patients with renal cell carcinoma,” (Abstract #4568). As of May 23, 2016, thirty-five renal cell carcinoma patients had been treated, including ten in combination with 10 mg daily everolimus, and twenty-five patients treated with CB-839 dosed as a monotherapy. In the combination group, the overall disease control rate was 80%, including one partial response; among eight clear cell and papillary patients, the disease control rate was 100%. The median time on study for these patients is currently 6.5+ months, exceeding the expected progression free survival of everolimus alone in this population. Time on treatment is currently equal to, or greater than the time on prior therapy for most patients, and seven of eight patients remain on study. The combination of CB-839 and everolimus has been well tolerated to date. There was one case of dose-limiting, grade 3 pruitic rash at the 400 mg dose level, which led to a reduction in the dose of everolimus for that patient. On the basis of this efficacy data, the company plans to continue development in combination therapy for renal cell carcinoma.

Among 21 efficacy evaluable patients treated as a monotherapy, 52% experienced stable disease or better, including one partial response. The monotherapy cohort represents an update from the data presented November 8, 2015 at the American Association of Cancer Research-NCI-EORTC conference.

CB-839 in Triple Negative Breast Cancer

Dr. Angela DeMichele from the University of Pennsylvania presented a poster titled, “Phase I study of CB-839, a small molecule inhibitor of glutaminase in combination with paclitaxel in patients with triple negative breast cancer,” (Abstract #1011). The abstract was also selected for a poster discussion presentation on Sunday, June 5, 2016. Eligible patients include locally advanced/metastatic TNBC, refractory disease, with prior paclitaxel allowed. As of May 23, 2016, fifteen triple negative breast cancer patients had been treated with doses of CB-839 of 400, 600 or 800 mg bid in combination with 80 mg/m^2 IV paclitaxel, weekly, three weeks out of four. The majority of patients had received at least three prior lines of therapy. Six patients received five or more prior therapies in the advanced/metastatic setting. Most patients had received prior taxanes in either the neo-adjuvant (n=7) or metastatic (n=5) setting. Among patients treated with CB-839 doses of at least 600 mg bid (n=8), there were 3 partial responses (38%) and disease control (response or stable disease) in 7 patients (88%). Two of the partial responses were observed in patients that were refractory to paclitaxel in a prior course of therapy. The combination of CB-839 and paclitaxel has been well tolerated to date, with adverse events that have been easily manageable and reversible, including several paclitaxel related toxicities. There was one case of dose-limiting, recurrent grade 3 neutropenia at the 400 mg dose level, which led to a reduction in the dose of paclitaxel for that patient.

Investor Event and Webcast

Calithera will host a conference call and webcast on Monday June 6, 2016, at 6:30 p.m. CT to review the clinical data presented at ASCO from the ongoing Phase I study of CB-839. The live audio webcast can be accessed via the Investor section of the Company's website at www.calithera.com. The conference call can be accessed by dialing (855) 783-2599 (domestic) or (631) 485-4877 (international) and refer to conference ID 23768811. Please log in approximately 5-10 minutes before the event to ensure a timely connection. The archived webcast will remain available for 30 days following the call.

About Calithera Biosciences

Calithera Biosciences, Inc. is a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer. Calithera’s lead product candidate, CB-839, is currently being evaluated in three Phase 1 clinical trials in solid and hematological cancers. CB-1158 is a first-in-class immuno-oncology metabolic checkpoint inhibitor targeting arginase, a critical immunosuppressive enzyme responsible for T-cell suppression by myeloid-derived suppressor cells. Arginase depletes arginine, a nutrient that is critical for the activation, growth and survival of the body’s cancer-fighting immune cells, known as cytotoxic T -cells. Calithera is headquartered in South San Francisco, California. For more information about Calithera, please visit www.calithera.com.

Forward Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "anticipate," "estimate," "intend," "poised" and similar expressions (as well as other words or expressions referencing future events, conditions, or circumstances) are intended to identify forward-looking statements. These statements include those related to the safety, tolerability and efficacy of CB-839, enrollment of the combination expansion cohorts of CB-839 and the presentation of additional combination data in 2016. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. The potential product candidates that Calithera develops may not progress through clinical development or receive required regulatory approvals within expected timelines or at all. In addition, clinical trials may not confirm any safety, potency or other product characteristics described or assumed in this press release. Such product candidates may not be beneficial to patients or successfully commercialized. The failure to meet expectations with respect to any of the foregoing matters may have a negative effect on Calithera's stock price. Additional information concerning these and other risk factors affecting Calithera's

business can be found in Calithera's most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission, and other periodic filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Calithera disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

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